

**Docket No. 2004N-0133: FDA Electronic Records;Electronic Signatures;
Public Meeting June 2004 : Comments from Syngenta Limited, Alderley Park**

In response to the FDA call for comments as part of the re-examination of part 11, Syngenta Limited, Alderley Park would respectfully submit the following comments for consideration.

A. Part 11 Subpart A-General Provisions

1. "whether part 11 should be revised to implement the narrow interpretation described in the guidance."

Response : We support the revision of Part 11 to include the narrow interpretation as we believe that systems which generate paper printouts of e-records should not trigger part 11.

3. "the need for clarification in part 11 regarding which records are required by predicate rules and are therefore required to be part 11 compliant."

Response : We believe that additional clarification is needed.

B. Part 11 Subpart B-Electronic Records (Individual Controls)

3. Should audit trail requirements include safeguards designed and implemented to deter, prevent, and document unauthorized record creation, modification and deletion?

Response : We consider that this additional requirement could have considerable cost implications. We also believe that if access to a system is restricted to authorised individuals and appropriate hierarchical levels are applied this kind of requirement is unnecessary.

D. Additional Questions for Comment

3. In what ways can part 11 discourage innovation?

Response : The need to carry out remedial action on legacy systems to make them comply with the Rule has meant that there has been no resource available to develop the systems in other ways and incorporate any additional user requirements.

6. Can the use of risk mitigation and appropriate controls eliminate concerns regarding legacy systems?

Response : We would support the use of controls and a risk-based approach to legacy systems as we consider that the criteria outlined in the Final Guidance Document for legacy systems are too strict to meet. We believe that using a risk-based approach would ease the financial burden of improving compliance of old systems.

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